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**Translation**

PATENT COOPERATION TREATY

**PCT**

INTERNATIONAL PRELIMINARY EXAMINATION REPORT

(PCT Article 36 and Rule 70)

6

Applicant's or agent's file reference MJPcb539/100	<b>FOR FURTHER ACTION</b> See Notification of Transmittal of International Preliminary Examination Report (Form PCT/IPEA/416)	
International application No. PCT/FR00/02611	International filing date ( <i>day/month/year</i> ) 20 September 2000 (20.09.00)	Priority date ( <i>day/month/year</i> ) 20 September 1999 (20.09.99)
International Patent Classification (IPC) or national classification and IPC C12N 15/52		
Applicant INSTITUT NATIONAL DE LA RECHERCHE AGRONOMIQUE (INRA)		

<p>1. This international preliminary examination report has been prepared by this International Preliminary Examining Authority and is transmitted to the applicant according to Article 36.</p> <p>2. This REPORT consists of a total of <u>6</u> sheets, including this cover sheet.</p> <p><input type="checkbox"/> This report is also accompanied by ANNEXES, i.e., sheets of the description, claims and/or drawings which have been amended and are the basis for this report and/or sheets containing rectifications made before this Authority (see Rule 70.16 and Section 607 of the Administrative Instructions under the PCT).</p> <p>These annexes consist of a total of _____ sheets.</p>	
<p>3. This report contains indications relating to the following items:</p> <p>I <input checked="" type="checkbox"/> Basis of the report</p> <p>II <input type="checkbox"/> Priority</p> <p>III <input checked="" type="checkbox"/> Non-establishment of opinion with regard to novelty, inventive step and industrial applicability</p> <p>IV <input type="checkbox"/> Lack of unity of invention</p> <p>V <input checked="" type="checkbox"/> Reasoned statement under Article 35(2) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement</p> <p>VI <input type="checkbox"/> Certain documents cited</p> <p>VII <input type="checkbox"/> Certain defects in the international application</p> <p>VIII <input type="checkbox"/> Certain observations on the international application</p>	

Date of submission of the demand 20 April 2001 (20.04.01)	Date of completion of this report 18 December 2001 (18.12.2001)
Name and mailing address of the IPEA/EP	Authorized officer
Facsimile No.	Telephone No.

## INTERNATIONAL PRELIMINARY EXAMINATION REPORT

International application No.

PCT/FR00/02611

## I. Basis of the report

## 1. With regard to the elements of the international application:\*

- ☒ the international application as originally filed
- ☒ the description:  
pages \_\_\_\_\_ 1-24 \_\_\_\_\_, as originally filed  
pages \_\_\_\_\_, filed with the demand  
pages \_\_\_\_\_, filed with the letter of \_\_\_\_\_
- ☒ the claims:  
pages \_\_\_\_\_ 1-16 \_\_\_\_\_, as originally filed  
pages \_\_\_\_\_, as amended (together with any statement under Article 19  
pages \_\_\_\_\_, filed with the demand  
pages \_\_\_\_\_, filed with the letter of \_\_\_\_\_
- ☐ the drawings:  
pages \_\_\_\_\_, as originally filed  
pages \_\_\_\_\_, filed with the demand  
pages \_\_\_\_\_, filed with the letter of \_\_\_\_\_
- ☒ the sequence listing part of the description:  
pages \_\_\_\_\_ 1-3 \_\_\_\_\_, as originally filed  
pages \_\_\_\_\_, filed with the demand  
pages \_\_\_\_\_, filed with the letter of \_\_\_\_\_

## 2. With regard to the language, all the elements marked above were available or furnished to this Authority in the language in which the international application was filed, unless otherwise indicated under this item.

These elements were available or furnished to this Authority in the following language \_\_\_\_\_ which is:

- ☐ the language of a translation furnished for the purposes of international search (under Rule 23.1(b)).
- ☐ the language of publication of the international application (under Rule 48.3(b)).
- ☐ the language of the translation furnished for the purposes of international preliminary examination (under Rule 55.2 and/or 55.3).

## 3. With regard to any nucleotide and/or amino acid sequence disclosed in the international application, the international preliminary examination was carried out on the basis of the sequence listing:

- ☐ contained in the international application in written form.
- ☐ filed together with the international application in computer readable form.
- ☒ furnished subsequently to this Authority in written form.
- ☒ furnished subsequently to this Authority in computer readable form.
- ☒ The statement that the subsequently furnished written sequence listing does not go beyond the disclosure in the international application as filed has been furnished.
- ☒ The statement that the information recorded in computer readable form is identical to the written sequence listing has been furnished.

4. ☐ The amendments have resulted in the cancellation of:

- ☐ the description, pages \_\_\_\_\_
- ☐ the claims, Nos. \_\_\_\_\_
- ☐ the drawings, sheets/fig \_\_\_\_\_

5. ☐ This report has been established as if (some of) the amendments had not been made, since they have been considered to go beyond the disclosure as filed, as indicated in the Supplemental Box (Rule 70.2(c)).\*\*

\* Replacement sheets which have been furnished to the receiving Office in response to an invitation under Article 14 are referred to in this report as "originally filed" and are not annexed to this report since they do not contain amendments (Rule 70.16 and 70.17).

\*\* Any replacement sheet containing such amendments must be referred to under item 1 and annexed to this report.

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## III. Non-establishment of opinion with regard to novelty, inventive step and industrial applicability

1. The questions whether the claimed invention appears to be novel, to involve an inventive step (to be non obvious), or to be industrially applicable have not been examined in respect of:

- ☐ the entire international application.
- ☒ claims Nos. 15, 16.

because:

- ☐ the said international application, or the said claims Nos. \_\_\_\_\_  
relate to the following subject matter which does not require an international preliminary examination (*specify*):

- ☒ the description, claims or drawings (*indicate particular elements below*) or said claims Nos. 15, 16  
are so unclear that no meaningful opinion could be formed (*specify*):

- ☐ the claims, or said claims Nos. \_\_\_\_\_ are so inadequately supported  
by the description that no meaningful opinion could be formed.

- ☐ no international search report has been established for said claims Nos. \_\_\_\_\_

2. A meaningful international preliminary examination cannot be carried out due to the failure of the nucleotide and/or amino acid sequence listing to comply with the standard provided for in Annex C of the Administrative Instructions:

- ☐ the written form has not been furnished or does not comply with the standard.
- ☐ the computer readable form has not been furnished or does not comply with the standard.

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**Supplemental Box**

(To be used when the space in any of the preceding boxes is not sufficient)

Continuation of: BOX III

1. The wording of Claim 15 is thoroughly unclear. It does not enable the reader to determine either the claimed subject matter or even the category to which the claim belongs.

The subject matter of Claim 16 concerns the use of the strain described in Claim 15. However, apart from the lack of clarity mentioned above, Claim 15 does not mention any strain.

Consequently, as a result of the total lack of clarity of Claims 15 and 16, no opinion can be provided as to the novelty, inventive step and industrial applicability of the subject matter of these claims.

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## V. Reasoned statement under Article 35(2) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement

### 1. Statement

Novelty (N)	Claims	12-14	YES
	Claims	1-11	NO
Inventive step (IS)	Claims		YES
	Claims	1-14	NO
Industrial applicability (IA)	Claims	1-14	YES
	Claims		NO

### 2. Citations and explanations

#### 1. The following documents are referred to:

D1: Journal of Bacteriology

Vol. 180, No. 15, pages 3804-3808, 1998

D2: Molecular Microbiology

Vol. 30, No. 4, pages 789-798, 1998

D3: Applied and Environmental Microbiology

Vol. 58, No. 3, pages 832-839, 1992.

2. D1 describes a recombinant *Lactococcus lactis* lactic acid bacterium genetically modified by transformation with a vector containing the nox-2 gene of *Streptococcus mutans*, enabling respiratory metabolism to be activated in this bacterium (summary). Consequently, the subject matter of independent Claims 1 and 10 is not novel in relation to D1.

D2 describes a *Lactococcus lactis* bacterium in which the CcpA gene has been deactivated (summary; page 790, columns 1 and 2, paragraph 2; column 2, paragraph 2). Consequently, the subject matter of independent Claim 1 is not novel in relation to D1.

D3 describes a bacterium I transformed by a vector

containing the catalase gene of *Lactobacillus sake* (summary; page 832, column 1, paragraph 2; page 836, column 1, paragraph 2).

Consequently, the subject matter of independent Claim 1 is not novel in relation to D3.

The objections concerning the independent claims also apply to the dependent claims referring to them. Consequently, the subject matter of Claims 1-11 is not novel.

It should be noted that regardless of D1-D3, the subject matter of Claims 1, 3 and 4 is not novel. Indeed, the subject matter of these claims concerns a recombinant lactic acid bacterium. Claims 1, 3 and 4 attempt to define this bacterium not in terms of technical features but in terms of a result to be achieved ("so as to provide it with..."; "resulting in..."), which cannot be considered to be a novel aspect of this bacterium. Consequently, the subject matter of Claims 1, 3 and 4 concerns a genetically modified recombinant lactic acid bacterium. Numerous genetically modified recombinant lactic acid bacteria are known from prior art (see in particular the description of the present application, Examples 2-5). The subject matter of the above-mentioned claims is therefore not novel.

Thus, Claims 1-11 do not meet the requirements of PCT Article 33(2).

3. The use of known products in accordance with known methods cannot be considered to be inventive. Consequently, the subject matter of Claims 10-14 is not inventive. Claims 10-14 therefore fail to meet the requirements of PCT Article 33(3).